

## **REMARKS**

Claims 1-21 are all of the pending claims, with claims 1, 18, and 20 being written in independent form.

### **I. Drawing Objections:**

At paragraph 2 of the Office Action, the Examiner objects to the drawings because reference characters “25” and “29” (appearing in Figs. 2 and 4) are not mentioned in the written description. To address the Examiner’s concerns, Applicant amends page 9 of the specification to designate the liquid impermeable foam plastic material with reference character “25” and the paper liner with reference character “29”. Applicant respectfully requests reconsideration and withdrawal of the raised drawing objections.

### **II. Specification Objection:**

At paragraph 3 of the Office Action, the Examiner objects to the specification because it does not include the usual section headings. Applicant appropriately amends the specification to address the Examiner’s concerns. Applicant respectfully requests reconsideration and withdrawal of the raised specification objection.

### **III. Claim Objections:**

The Examiner objects to numerous claims for the reasons noted at paragraph 4 of the Office Action. As a path of least resistance, and without acquiescing to the correctness of the objections, Applicant amends the claims by incorporating the Examiner’s helpful suggestions. Applicant respectfully requests reconsideration and withdrawal of the raised claim objections.

### **IV. Claim Rejections on Prior Art Grounds:**

The Examiner rejects:

1. claims 1, 11, 15 and 18-20 under 35 USC §103(a) as being obvious over US 5,044,372 to Anhäuser et al. (“Anhäuser”) in view of US 6,143,945 to Augustine et al. (“Augustine”);

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2. claims 2-4, 17 and 21 under 35 USC §103(a) as being obvious over Anhäuser and Augustine, and further in view of US 4,887,611 to Rüdiger et al. ("Rüdiger");
3. claim 5 under 35 USC §103(a) as being obvious over Anhäuser and Augustine, and further in view of US 4,450,844 to Quisno ("Quisno");
4. claim 6 under 35 USC §103(a) as being obvious over Anhäuser and Augustine, and further in view of US RE37,934 to Hoffmann ("Hoffmann");
5. claim 7 under 35 USC §103(a) as being obvious over Anhäuser and Augustine, and further in view of US 4,543,964 to Breneman ("Breneman");
6. claim 8 under 35 USC §103(a) as being obvious over Anhäuser and Augustine, and further in view of NL 8701577 to van der Bend ("van der Bend");
7. claims 9, 12 and 13 under 35 USC §103(a) as being obvious over Anhäuser and Augustine, and further in view of US 4,472,507 to Pluim, Jr. ("Pluim");
8. claims 10 and 14 under 35 USC §103(a) as being obvious over Anhäuser and Augustine, and further in view of US 4,158,359 to Kurokawa et al. ("Kurokawa"); and
9. claim 16 under 35 USC §103(a) as being obvious over Anhäuser and Augustine, and further in view of US 4,809,707 to Kraft et al. ("Kraft").

Applicant respectfully traverses all of these rejections in view of the following remarks.

**A. Independent Claims 1, 18 and 20:**

Each of independent claims 1, 18 and 20 recites (albeit in different formats) the following two features:

- (1) a "*frame-shaped foam plastic layer*" provided on a support element; and
- (2) a "*layer of adhesive*" (or "*adhesive means*") provided on the frame-shaped foam plastic layer.

An example, non-limiting embodiment of these features is depicted in Fig. 2. Here, a frame-shaped element 24 is secured on top of the support element 17. The frame-shaped element 24 includes a frame-shaped foam plastic layer 25, and a layer of adhesive 26 is provided on the outer side (or upper side in Fig. 2) of the frame-shaped foam plastic layer 25.<sup>1</sup> At least these features (as recited in each of independent claims 1, 18 and 20), in combination with the other features recited in independent claims 1, 18 and 20, are not taught or suggested by the prior art relied upon by the Examiner.

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<sup>1</sup> Spec., p. 9, lines 1-9.

The Examiner recognizes that Anhäuser is not pertinent to the claimed “*layer of adhesive*” (or “*adhesive means*”), and therefore looks to Augustine to allegedly teach this feature. In so doing, the Examiner concludes that it would have been obvious to a skilled artisan to place Augustine’s adhesive layer 28 (see Figs. 1A and 1B) on the outwardly directed side of Anhäuser’s locking ring 15 “*to achieve the predictable result of creating a closed, fluid impermeable chamber.*”<sup>2</sup> This rejection position is not convincing for several reasons.

#### New Examination Guidelines

Based on the details of the rejection, it is apparent that the Examiner looks to the new examination guidelines for determining obviousness under 35 USC §103 in view of the Supreme Court decision in *KSR International Co. v. Teleflex Inc.*<sup>3</sup> This is because the new guidelines include a list of rationales that may be used to support a finding of obviousness. And one of the listed rationales involves combining prior art elements according to known methods to yield predictable results.<sup>4</sup> This rationale requires (among other things) satisfaction of a four part test. In the situation at hand, however, at least the first part of the four part test is *not satisfied*.

In particular, the first part of the test requires that the prior art included each element claimed, with the *only difference* between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference. Here, the Examiner attempts to compare Augustine’s adhesive layer 28 to the claimed adhesive layer. As shown in Fig. 1A and 1B of Augustine, the adhesive layer 28 is provided on a fluid-impermeable barrier 26.<sup>5</sup> Augustine does not, however, indicate the specific materials from which the barrier 26 may be fabricated. Thus, it cannot be determined with any amount of certainty that Augustine’s adhesive layer 28 is provided on a side of a frame-shaped “*foam plastic*” layer, as claimed. In this regard, the rejection grounds are tenable only by placing a strained interpretation on Augustine that could be made by only inappropriate hindsight.

Applicant notes that Augustine discloses an alternative embodiment in which the barrier 26 may be altogether eliminated, and the adhesive layer 28 may be provided directly

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<sup>2</sup> Office Action, paragraph 10.

<sup>3</sup> The new examination guidelines are set forth in the Federal Register, vol. 72, no. 195, p. 57526-57535, October 10, 2007.

<sup>4</sup> *Id.* at 57529.

<sup>5</sup> Augustine, col. 5, lines 4-6.

on the bandage 10.<sup>6</sup> Further, the bandage 10 may be fabricated from foam material such as polyurethane.<sup>7</sup> Here, however, the adhesive layer 28 is still not pertinent because the bandage 10 is not “*frame-shaped*,” as claimed.

In short, the asserted references disclose numerous and varied adhesive layers, but none is provided on an outwardly directed side of a “*frame-shaped foam plastic layer*,” as claimed. This difference in location is significant because it is in addition to the lack of actual combination of the claim elements in a single reference (which is the *only difference* permitted by the test).

No Valid Reason To Make The Alleged Combination

The Examiner has not identified a valid reason that would have prompted an artisan to make the alleged combination. According to the Examiner, it would have been obvious to modify Anhäuser (by incorporating Augustine’s adhesive layer) to achieve the “*predictable result of creating a closed, fluid impermeable chamber*.”<sup>8</sup> *Create a closed, fluid impermeable chamber?* This is simply not understood because Anhäuser’s epicutaneous test plaster (without any modification whatsoever) *already provides such a chamber*. Indeed, as background, Anhäuser expressly indicates that it is desirable to provide a plaster that is “*watertight*,” but that watertightness cannot be realized using conventional structures.<sup>9</sup> Anhäuser overcomes the shortcomings associated with conventional structures (including the inability to provide watertightness) by providing a carrier film 12 that is fabricated from an elastic material that is “*tight for liquid water*.”<sup>10</sup> As shown in Fig. 1, the carrier film 12 supports a contact adhesive layer 13 that (upon application) adheres together the carrier film 12 and the test area ... resulting in a fluid tight enclosure within the locking ring 15.<sup>11</sup> Accordingly, those skilled in the art would not have been prompted to implement the alleged combination because doing so would have served no apparent purpose.

Turning to the next point, the new examination guidelines indicate that it can be important to identify a reason that would have prompted an artisan to make the alleged combination.<sup>12</sup> Indeed, in the underlying KSR case, the Supreme Court rejected the Federal

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<sup>6</sup> Augustine, col. 5, lines 46-52.

<sup>7</sup> Augustine, col. 5, lines 21-22.

<sup>8</sup> Office Action, paragraph 10.

<sup>9</sup> Anhäuser, col. 1, lines 43-50.

<sup>10</sup> Anhäuser, col. 1, lines 55-57.

<sup>11</sup> See Anhäuser, col. 3, lines 12-21.

<sup>12</sup> Federal Register, vol. 72, no. 195, p. 57529.

Circuit's perceived rigid application of the teaching, suggestion or motivation test in favor of a more expansive and flexible approach, which requires a determination of whether there is an "*apparent reason*" to combine the known elements from the prior art in the claimed manner.<sup>13</sup> Furthermore, the analysis should be made explicit.<sup>14</sup> In summing up the obviousness rational in the KSR case, the Supreme Court concluded that a person having ordinary skill in the art could have combined the prior art elements in a fashion encompassed by the claim at issue, "*and would have seen the benefits of doing so.*"<sup>15</sup> In the situation at hand, those skilled in the art would not have seen any benefit in making the alleged combination.

As demonstrated above, those skilled in the art would not have been prompted to make the alleged combination to create a closed, fluid impermeable chamber because Anhäuser's epicutaneous test plaster (without any modification whatsoever) already provides a closed, fluid impermeable chamber. In this regard, the alleged combination would have been superfluous. There is no apparent reason to make the alleged combination of elements.

#### References Teach Away From Any Combination

In this case, the references take mutually exclusive paths and reach different solutions to practically and conceptually different problems. On the one hand, the primary reference to Anhäuser teaches a *diagnostic test device* including a receiving device 14 that is loaded with a test substance.<sup>16</sup> The intended purpose of the device is to apply the test substance to a patient's skin. On the other hand, the secondary reference to Augustine teaches a *therapeutic device* in the form of a non-contact bandage. The intended purpose of the device is to absorb exudates produced at a wound.<sup>17</sup> The two concepts (i.e., supplying a test substance to the skin *versus* absorbing exudates from the skin) are fundamentally different, and therefore it would not be logical to combine the references in the manner suggested by the Examiner.

#### The Alleged Combination is Not Pertinent

Even if Augustine's adhesive layer 28 were provided on Anhäuser's locking ring 15 (as suggested by the Examiner), the rejection position would still be incorrect. This is because Anhäuser describes the locking ring 15 as a "*film ring*", "*film material locking ring*"

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<sup>13</sup> *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741.

<sup>14</sup> *Id.*

<sup>15</sup> *Id.* at 1743.

<sup>16</sup> See Anhäuser, col. 1, lines 6-24.

<sup>17</sup> Augustine, col. 6, lines 1-7.

and “*polyester film locking ring*.”<sup>18</sup> Such terms do not (in any way) teach or suggest that the locking ring 15 is “*foam plastic*,” as claimed. Indeed, as is well known in this art, the term “*film*” refers to a thin sheet of compact material, while the term “*foam*” refers to a lightweight material in cellular form; made by introducing gas bubbles during manufacture. Certainly then, the two terms are practically and conceptually different. In this regard, the rejection grounds involve an incorrect comparison of apples to oranges.

**B. Dependent Claims 2 and 21:**

Each of dependent claims 2 and 21 recites that the cover layer is a plastic layer with “*blister bubbles*.” An example, non-limiting embodiment of this feature is depicted in Fig. 3. Here, the blister bubble is designated with reference character 33. At least this feature (as recited in each of claims 2 and 21), is not taught or suggested by the prior art relied upon by the Examiner.

The Examiner recognizes that Anhäuser and Augustine are not pertinent to the claimed blister bubbles, and therefore looks to Rüdiger to allegedly teach this feature. In so doing, the Examiner concludes that those skilled in the art would have used a cover layer with Rüdiger’s dome 20 “*to improve handling, storage and transport of the plaster*.”<sup>19</sup> This rejection position is not convincing.

According to Rüdiger’s straightforward disclosure, the improved handling storage and transport features result from the plaster being enveloped in a protective pack consisting of an upper foil and a lower foil that enclose the test plaster in sandwich fashion.<sup>20</sup> That is, the improvements result from much more than just the dome 20 of the upper foil. Accordingly, if one skilled in the art desired to obtain Rüdiger’s advantages (as alleged by the Examiner), then it would be necessary to make a series of separate, awkward combinative steps that are far too involved to be considered obvious.

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<sup>18</sup> Anhäuser, col. 3, line 16; col. 4, line 38; and col. 5, line 34.

<sup>19</sup> Office Action, paragraph 14.

<sup>20</sup> Rüdiger, col. 3, lines 39-44.

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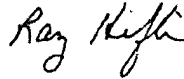
**CONCLUSION**

In view of the above, Applicant earnestly solicits reconsideration and allowance of all of the pending claims.

Pursuant to 37 CFR §§ 1.17 and 1.136(a), Applicant petitions for a one (1) month extension of time for filing a reply to the Office Action and submit the required \$60.00 extension fee herewith.

The Commissioner is authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 50-3777 for any additional fees required under 37 CFR § 1.16 or under 37 CFR § 1.17; particularly, extension of time fees.

Respectfully submitted,



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